UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/559,098 | 01/10/2007 | Mario Leclerc | GENOM.071NP | 1280 |

20995 7590 06/18/2009

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

| EXAMINER | |
|---|---|
| PITRAK, JENNIFER S | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1635 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 06/18/2009 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/559,098 | LECLERC ET AL. | |
| | Examiner | Art Unit | |
| | JENNIFER PITRAK | 1635 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *07 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,4-26 and 35-38* is/are pending in the application.

4a) Of the above claim(s) *5,6,9-26 and 35-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,7,8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/18/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Remarks*

Claims 1, 4-26, and 35-38 are pending. Claims 5, 6, 9-26, and 35-38 are withdrawn from consideration as being directed to non-elected subject matter. Claims 1, 4, 7, and 8 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Priority*

Claims 7 and 8 are provided the benefit of the filing date of PCT/CA04/00824, which is 06/03/2004, for the reasons of record. Claims 1 and 4 are provided the benefit of the filing date of the provisional application 60/474,950, which is 06/03/2003, for the reasons of record.

### *Claim Rejections - 35 USC § 112 - withdrawn*

The amendments to the claims have obviated the rejection of claims 4, 7, and 8 under 35 U.S.C. 112, second paragraph, as being indefinite. Therefore, the rejection is withdrawn.

### *Claim Rejections - 35 USC § 103 - Maintained*

Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ho, *et al.* (2002, item 16 on 12/01/2005 IDS) and Gold (1996, JBC, v.270:13581-4, of record). This rejection is maintained for the reasons of record.

**Response to arguments**

Applicant argues that Ho et al. teach that polythiophene derivatives can be used to detect specific single-stranded oligonucleotides by using a polythiophene derivative and a "capture probe" that is a single stranded oligonucleotide substantially complementary to the target ssDNA and that Ho et al. teach the use of water-soluble polythiophene derivatives to "transduce oligonucleotide hybridization with a specific 20-mer capture probe into a clear optical (colorimetric or fluorometric) output." Applicant concludes that, at most, the skilled artisan would conclude from Ho, et al. that the polythiophene derivatives could be used to detect ssDNA targets that hybridize to the capture probe or capture aptamer (page 8 of 04/07/09 response) and that, therefore, one would not expect success in using the polythiophene derivatives to detect the targets recited in claim 1. This is not persuasive because "nucleotides" are recited as a target in claim 1, and the detected oligonucleotides in the Ho reference are comprised of nucleotides. Applicant's further argument that the Gold reference does not cure the deficiencies of Ho, et al. because Gold does not mention polythiophene derivatives is not persuasive because Gold is relied upon to teach aptamers, not polythiophene derivatives, as indicated in the rejection of record.

***Claim Rejections - 35 USC § 103 - Withdrawn***

The rejection of claims 7 and 8 under 35 U.S.C. 103(a) as being unpatentable over Ho, *et al.*, Gold, Michaud, *et al.* (02/15/2004, Analytical Chemistry, V.74:1015-20) is withdrawn. Applicant's arguments were persuasive.

***Claim Rejections - 35 USC § 103 - New***

Claims 1, 4, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michaud, *et al.* (02/15/2004, Analytical Chemistry, V.74:1015-20, of record), Ho, *et al.* (2002, item 16 on 12/01/2005 IDS), McQuade, *et al.* (2000, item 22 on 02/18/2009 IDS), Gold (1996, JBC, v.270:13581-4, of record), and Nilsson, et al. (2002, item 24 on 02/18/2009 IDS).

Ho, et al. teach an optical sensor for detecting a target comprising a ssDNA complementary to the target and the water-soluble cationic polythiophene derivative of the formula shown in claim 1 (see Scheme 1, Polymer 1 on page 1549). Ho, et al. teach the use of this optical sensor for detecting a nucleic acid target (p. 1550, first column) and that the optical sensors could be used for the detection of DNA-hybridization events (p.1551, first column). Ho, et al. do not teach that the ssDNA of their optical sensor is an aptamer.

Michaud, *et al.* teach the D-adenosine-specific aptamer having the precise sequence of the instantly claimed SEQ ID NO: 3 (Figure 1, "ADE"). Michaud, *et al.* teach that the D-adenosine-specific aptamer was useful for distinguishing between the adenosine enantiomers, D-adenosine and L-adenosine (p.1016, bottom of right column; p.1017, Figure 2). Michaud, *et al.* also teach that enantiomeric separation is important in several scientific fields and that aptamers are useful as sensors (p.1015).

McQuade, et al. teach biosensors comprised of polythiophenes and antibodies for detecting an analyte (p.2567 and Figure 24).

Gold teaches that aptamers are ssDNA molecules that interact with target molecules (p. 13581, first paragraph and first paragraph of second column). Gold also teaches that the aptamers are useful for detecting proteins and that the aptamers can be modified with visualization-enhancing adducts and reporters (p. 13583, "Uses of Molecules Derived from SELEX"). Gold

teaches that aptamers are as potent as antibodies with respect to affinities and specificities (p.13583, first paragraph).

Nilsson, et al. teach that conjugated polythiophene can be used to couple analyte-receptor interactions into observable responses and that the conjugated polythiophene sensors are very sensitive to very minor perturbations (p.10011, introduction).

It would have been obvious to one skilled in the art at the time of the instant application to make a polythiophene-ssDNA optical sensor complex for detecting a target molecule, as taught by Ho, et al. It further would have been obvious to use the aptamer having SEQ ID NO: 3 in place of the ssDNA molecule in the optical sensor complex of Ho, et al. because Michaud, et al. teach that SEQ ID NO: 3 is an aptamer useful for detecting the enantiomer, D-adenosine, and that aptamers are useful as sensors. One of skill in the art would be motivated to use the D-adenosine aptamer in an optical sensor because Michaud, et al. teach that resolution of enantiomers is important in fields such as drug and food analysis, biochemistry, and clinical pharmacology. One of skill in the art would recognize that the use of polythiophene in an aptamer-based sensor would function because McQuade, et al. teaches that polythiophene-antibody complexes are effective biosensors and Gold teaches that aptamers are as potent as antibodies with respect to affinity and specificity. One would also expect that an aptamer-polythiophene sensor would function because Nilsson, et al. teach that polythiophene sensors are very sensitive to minor perturbations.

**Response to relevant arguments**

Applicant argues that Ho et al. teach that the hybridization of the capture probe and target to form a dsDNA is essential for the detection via the polythiophene derivative and that therefore, at most, one skilled in the art would conclude from Ho et al. that the polythiophene

derivatives could be used to detect ssDNA targets that hybridize to the capture probe/aptamer (4/7/09 response page 8). This is not persuasive because McQuade, et al. teach that polythiophenes can be used with antibodies, which can be substituted with aptamers, and Nilsson, et al. teach that polythiophenes are very sensitive to even minor perturbations. One of skill in the art would recognize that aptamer binding to its target analyte would result in at least a minor perturbation of the aptamer such that the polythiophene would likely yield a detectable signal. Alternatively, one of skill would recognize that the polythiophene-aptamer sensor could be used as in the polythiophene-antibody sensor taught by McQuade, et al.

***Conclusion***

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 02/18/2009 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER PITRAK whose telephone number is (571)270-3061. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Pitrak
Examiner
AU 1635

/Sean R McGarry/
Primary Examiner, Art Unit 1635